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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/398,253	09/17/1999	MICHAEL NEHLS	8535-026-999	9822

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EXAMINER	
KIM, YOUNG J	

ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 01/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	09/398,253	NEHLS ET AL.	
	Examin r	Art Unit	
	Young J. Kim	1637	

--The MAILING DATE of this communicati n appears on the cover sheet with the correspondence address --

THE REPLY FILED 31 December 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☐ The period for reply expires _____months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1.☒ A Notice of Appeal was filed on *31 December 2003*. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2.☐ The proposed amendment(s) will not be entered because:

(a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

(b) ☐ they raise the issue of new matter (see Note below);

(c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

(d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____.

3.☐ Applicant's reply has overcome the following rejection(s): _____.

4.☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5.☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *See Continuation Sheet*.

6.☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7.☐ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: _____.

Claim(s) withdrawn from consideration: _____.

8.☐ The drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9.☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10.☐ Other: _____

Continuation of 5. does NOT place the application in condition for allowance because: The rejection of claims 1, 3, 4, 10, and 12 under 3 U.S.C. 101 because the claimed invention is not supported by either a specific and/or substantial asserted utility or a well established utility, made FINAL in the Office Action mailed on July 2, 2003 is maintained for the reasons of record. Applicants' arguments presented in the After Final Amendment received on December 31, 2003 have been fully considered but they are not found persuasive for the following reasons. Applicants' arguments are addressed in the order they were presented. On page 2, Applicants argue that the claimed oligonucleotides and polynucleotides do not have a general utility but a specific utility because the gene trap method, "enriches for a class of genes that are not required for tetracarcinoma cell viability and are likely to be involved in late stages of cellular differentiation and development (page 2, Response). As Office Action mailed on July 2, 2003 already addressed, the claimed nucleic acids and oligonucleotides lack a substantial, immediately apparent, utility.

On page 3, Applicants argue that the claimed polynucleotides can be used as a gene probe or chromosome marker specific for such genes that are of particular interest to scientists and medical practitioner "studying the biology of cellular differentiation and development. The fact that medical practitioner can use the claimed invention for "studying the biology of cellular differentiation and development," clearly demonstrates that the claimed invention lacks an immediately apparent utility, other than conducting further research on the claimed invention. When further research is needed to reasonably identify a utility that is immediately apparent, it is a clear evidence that an immediately apparent utility has not been determined. Although Applicants have isolated a subset of nucleic acids via use of gene trap vectors, Applicants have not provided to one skilled in the art what the isolated nucleic acids are immediately useful for, other than conducting further research to identify such usefulness. Such is evident in Applicants' arguments. For example, in Applicants' response received on April 7, 2003, on page 4, Applicants argue that the gene trap method allows one to identify genes that do not have an easily observable phenotype. However, neither the specification nor the Applicants response discloses what phenotypes are associated with th claimed nucleic acids. A skilled artisan reading both the instant specification and Applicants' response, therefore, would only be led to conduct further experimentation on the nucleic acids to identify what phenotypes are correlated with the claimed nucleic acids.

On page 3, Applicants contend that page 12, lines 8-24 of the specification discloses specific and substantial utility for the claimed invention. Although Applicants have listed a plethora of utilities that are known in the art which are applicable to nucleic acids in general, no substantial utility, that is, how the listed utilities are correlated to the claimed nucleic acids, has been disclosed. In other words, the specification lacks description on why the claimed nucleic acids should be used in, for example, a gene expression analysis. Unless a skilled artisan conducts further experimentation (expression analysis) on the claimed nucleic acid, the skilled artisan would not be able to determine what is meant by its presence/absence or overexpression/repression. Only after conducting further research, a skilled artisan would be able to arrive at a "successful conclusion" of what the claimed nucleic acids would be immediately useful for. On page 12, line 12, the specification recites that the claimed nucleic acids could be useful for antisense therapy, but fails to give any more description on what condition the claimed nucleic acids are to alleviate/inhibit. Based on this description, a skilled artisan, again, would have to conduct further experimentation to determine whether or not there is a correlation between the claimed nucleic acid and a medical condition, and i there is, whether or not the claimed nucleic acids could be useful as an antisense. Clearly, the plainly apparent need for further experimentation evidences that Applicants have not arrived at an immediately apparent utility, but only a starting point from which to conduct further experimentation.

If Applicants arguments were valid, any nucleic acid isolated from a brain tissue "could" be useful an array of well known utilities, such as expression analysis, gene therapy, chromosome marker, drug discovery, diagnostic, etc. In other words, any nucleic acid has the potential to be useful for any assays involving nucleic acids. However, for substantial utility to be satisfied, the disclosure must make apparent a utility that is specific, substantial or well established. As set forth above, the specification fails to disclose any correlation between the claimed nucleic acid and a list of utilities in a substantial way (i.e., immediately apparent utility). Rather, the specification asserts an array of utilities that apply to nucleic acids in general. The court in Kirk (at page 53) held:

"We do not believe that it was the intention of the statutes to require the Patent Office, the courts, or the public to play the sort of guessing game that might be involved if an applicant could satisfy the requirement for statutes by indicating the usefulness of a claimed compound in terms of possible use so general as to be meaningless and then, after his research or that of his competitors has definitely ascertained an actual use for the compound, adducing evidence intended to show that a particular specific use would have been obvious to men skilled in the particular art to which this use relates."

Analogously, the instant specification fails to make a substantial correlation of the claimed nucleic acids to a list of utilities that are applicable to nucleic acids in general, rendering the claimed nucleic acid lacking in their substantial utility.

Applicants argue that the credibility of Applicants' assertion has been questioned. This argument is not found persuasive because the Office Action is clear in indicating that the claimed nucleic acid lacks a substantial utility. Applicants' assertion is generally applicable to any nucleic acids. For example, Applicants assert that the claimed nucleic acid could be useful for diagnostic gene expression analysis, but fail to disclose what the presence/absence or overexpression/repression would reveal to a skilled artisan. Another assertion provided by Applicants is that the claimed nucleic acids could be useful as an antisense, but fails to disclose what the conditions the antis nse is to alleviate/treat, etc. The instant specification does not provide any correlation of the claimed nucleic acids to the list of possible utilities, thereby failing to disclose a substantial utility for the claimed invention.

Applicants argue that the use of claimed nucleic acids help cut down the total number of genes that needs to be studied and simplify the work of a biologists who uses this research tool to study embryonic cell differentiation and development. Applicants are advised that according to MPEP 2107.01(a), a basic research tool such as studying the properties of the claimed product itself or the mechanisms in which the material is involved lacks substantial utility. Clearly according to Applicants statement, the claimed nucleic acids are used as a research tool to study the properties of the nucleic acids and the mechanisms in which the claimed nucleic acids are involved.

Although Applicants have provided a list of utilities that are applicable to nucleic acids in general, such as in hybridization assays, gene delivery/therapy, probes/markers, antisense, as set forth above, no substantial correlation has been made between the claimed nucleic acids and the list of possible utilities, rendering the claimed nucleic acids lacking in a substantial, immediately apparent utility.

For the above reasons, the rejection is maintained.

The rejection of claims 1, 3, 4, 10, and 12 under 35 U.S.C. 112, first paragraph because the claimed invention is not supported by either a specific and substantial utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention, made FINAL in the Office Action mailed on July 2, 2003 is maintained for the reasons of record. Applicants' arguments received on December 31, 2003 have been fully considered, but are not found persuasive because the claimed nucleic acids are determined to lack a substantial utility as set forth above.

The rejection of claims 1, 3, 4, 10, and 12 under 35 U.S.C. first paragraph as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, made FINAL in the Office Action mailed on July 2, 2003 is maintained for the reasons of record.

Applicants' arguments received on December 31, 2003 have been fully considered but they are not found persuasive for the reasons below.

Applicants argue that the law does not require the applicant to describe exactly the subject matter claimed as long as the description clearly allows persons of ordinary skill in the art to recognize that he or she invented what is claimed (page 6). The issue at hand is whether Applicants were in possession of the genus being claimed, that is the sequence of a full-length cDNA comprising the claimed nucleic acids. While it is acknowledged that Applicants need not describe "every nuance" of the claimed invention, the written description must bear a reasonable correlation to what is claimed. The genus of nucleic acid molecules embraced by the claims includes every type of nucleic acid molecules that comprise the claimed SEQ ID Numbers, and additional sequences of any size and sequence. Clearly at th time of filing, Applicants were not in possession of genomic materials that contain the claimed nucleic acid fragment, which are embraced by the open-ended language of the claims. The specification does not disclose what characteristics these additional sequences may or may not have that are consistent with the operability of the nucleic acid molecules as probes or primers for detection of the SEQ ID Numbers in a target sequence, and all disclosed uses for the claimed nucleic acid molecules are fundamentally as probes or markers, at least in some aspect. The specification does not disclose encoding sequences or open reading frames (ORFs) and the fundamental issu here is specific to the very narrow class of product that is nucleic acid molecules. The basic question upon which Applicants and the Examiner disagree is whether the disclosure of a partial sequence of otherwise uncharacterized nucleic acid molecules that may encode corresponding protein is sufficient to establish possession of a broad genus based solely on the description of the partial sequence, wher the broad genus embraces the uncharacterized nucleic acid molecules by default. The specification fails to provide structural or functiona characteristic for these desired nucleic acids, which encode the protein, that would distinguish them from the other members of the genus which simply comprise the claimed SEQ ID Numbers as the sole distinguishing feature. As stated in University of California v. Eli Lilly an Co. at page 1404:

An adequate written description of DNA..."requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. Fiers v. Revel, 984 F.2d 1164, 1171, 25 USPQ2d 1601 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id. at 1170, 25 USPQ2d a 1606.

The Applicants' claims embrace nucleic acid molecules that encode a corresponding protein, whatever it may be, is clearly evident from the claimed language chosen. The Court in University of California v. Eli Lilly and Co, at page 1405, further noted regarding generic claims:

A written description of an invention involving a chemical genus, like a description of a chemical species, "requires a precise definition, such as by structure, formula, [or] chemical name," of the claimed subject matter sufficient to distinguish it from other materials. Fiers, 984 F.2d at 1171 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus...").

In the instant case, the only species specifically enumerated are the nucleic acids of claimed SEQ ID Numbers. The specific embodiments that in addition to the claimed SEQ ID Numbers include nucleic acids that will allow the corresponding protein to be encode cannot be predicted without the coding sequence itself. This coding sequence has not been disclosed. Clearly, the specification would not show one skilled in the art that these desired subcombinations were possessed by the Applicants, and thus the embracing genus was also not possessed.

Therefore, for the above reasons, the rejection is maintained.

KENNETH R. HORLICK, PH.D
PRIMARY EXAMINER
1/22/04